FORM PTO-1390 (REV. 11-2000) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 3868-0111P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/070657 NEW

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/08332	August 26, 2000	September 10, 1999

TITLE OF INVENTION
PLASTIC FILMS, ESPECIALLY FOR USE IN A DERMAL OR TRANSDERMAL THERAPEUTIC SYSTEM

APPLICANT(S) FOR DO/EO/US
KLEIN, Robert-Peter; MECONI, Reinhold; GOTTE, Ursula

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U S C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U S C 371
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is transmitted herewith.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 20. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form PTO-1449(s), and International Search Report (PCT/ISA/210) with 0 document(s).
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
    1.) PCT/IPEA/416
    2.) PCT/IPEA/409

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
NEW 10/070657	PCT/EP00/08332	3868-0111P

21. ☒ The following fees are submitted.	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. **$1,040.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO. **$740.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4). **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ **890.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ **130.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	11 - 20 =	0	X **$18.00**	$ **0.00**	
Independent Claims	1 - 3 =	0	X **$84.00**	$ **0.00**	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		NO	+ **$280.00**	$ **0.00**	
			TOTAL OF ABOVE CALCULATIONS =	$ **1020.00**	
☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				$ **0.00**	
			SUBTOTAL =	$ **1020.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐20 ☐30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$ **0.00**	
			TOTAL NATIONAL FEE =	$ **1020.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ **0.00**	
			TOTAL FEES ENCLOSED =	$ **1020.00**	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $ **1020.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:
Birch, Stewart, Kolasch & Birch, LLP or Customer No. 2292
P.O. Box 747
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Date: March 8, 2002

By: James M. Slattery
James M. Slattery, #28,380

/ka

PATENT
3868-0111P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: KLEIN, Robert-Peter et al.

Int'l. Appl. No.: PCT/EP00/08332

Appl. No.: NEW Group:

Filed: March 8, 2002 Examiner:

For: PLASTIC FILMS, ESPECIALLY FOR USE IN A DERMAL OR TRANSDERMAL THERAPEUTIC SYSTEM

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

March 8, 2002

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert --This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/EP00/08332 which has an International filing date of August 26, 2000, which designated the United States of America.--

Docket No. 3868-0111P

IN THE CLAIMS:

Please amend the claims as follows:

3. (Amended) Therapeutic system according to Claim 1, characterized in that the vapour-deposited metal is aluminium.

4. (Amended) Therapeutic system according to Claim 1, characterized in that the plastic films of the protective layer, which are provided with a vapour-deposited metal layer, are rendered adhesive on at least one side.

5. (Amended) Therapeutic system according to Claim 1, characterized in that the plastic films are selected from the group of polyester, polyethylene, polypropylene, polyamide, polyurethane, polyvinyl chloride, polyvinylidene chloride, polyvinyl alcohol and ethylene-vinyl acetate copolymer.

6. (Amended) Therapeutic system according to Claim 1, characterized in that the plastic films have a thickness between 0.004 to 1.0 mm, preferably between 0.010 and 0.5 mm.

7. (Amended) Therapeutic system according to Claim 1, characterized in that it contains nitroglycerine as ingredient.

8. (Amended) Therapeutic system according to Claim 1, characterized in that it contains nicotine as ingredient.

9. (Amended) Process for the manufacture of plastic films, provided with a vapour-deposited metal layer, for transdermal therapeutic systems according to Claim 1, characterized in that to obtain absolutely impermeable double-face metal layers, the vapour deposition is performed under high vacuum in at least one operation.

10. (Amended) Process for the manufacture of plastic films, provided with a vapour-deposited metal layer, for transdermal therapeutic systems according to Claim 1, characterized in that to obtain absolutely impermeable metal layers, the vapour deposition is performed with the aid of a plasma in at least one operation.

11. (Amended) Use of plastic films according to Claim 1 for manufacturing dermal or transdermal therapeutic systems containing readily volatile active agents or auxiliary agents.

Docket No. 3868-0111P

REMARKS

The specification has been amended to provide a cross-reference to the previously filed International Application.

The claims have also been amended to remove the multiple dependencies in order to place the application into better form prior to examination.

Entry of the present amendment and favorable action on the above-identified application are earnestly solicited.

Attached hereto is a marked-up copy of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
James M. Slattery, #28,380

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JMS/ka
3868-0111P

Attachment: VERSION WITH MARKINGS TO SHOW CHANGES MADE

(Rev. 02/21/02)

Docket No. 3868-0111P

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

3. (Amended) Therapeutic system according to [one or more of Claims 1 to 2] Claim 1, characterized in that the vapour-deposited metal is aluminium.

4. (Amended) Therapeutic system according to [one or more of Claims 1 to 3] Claim 1, characterized in that the plastic films of the protective layer, which are provided with a vapour-deposited metal layer, are rendered [abhesive] adhesive on at least one side.

5. (Amended) Therapeutic system according to [one or more of Claims 1 to 4] Claim 1, characterized in that the plastic films are selected from the group of polyester, polyethylene, polypropylene, polyamide, polyurethane, polyvinyl chloride, polyvinylidene chloride, polyvinyl alcohol and ethylene-vinyl acetate copolymer.

6. (Amended) Therapeutic system according to [one or more of Claims 1 to 5] Claim 1, characterized in that the plastic films have a thickness between 0.004 to 1.0 mm, preferably between 0.010 and 0.5 mm.

7. (Amended) Therapeutic system according to [one or more of Claims 1 to 6] Claim 1, characterized in that it contains nitroglycerine as ingredient.

8. (Amended) Therapeutic system according to [one or more of Claims 1 to 6] Claim 1, characterized in that it contains nicotine as ingredient.

9. (Amended) Process for the manufacture of plastic films, provided with a vapour-deposited metal layer, for transdermal therapeutic systems according to [one or more of Claims 1 to 8] Claim 1, characterized in that to obtain absolutely impermeable double-face metal layers, the vapour deposition is performed under high vacuum in at least one operation.

10. (Amended) Process for the manufacture of plastic films, provided with a vapour-deposited metal layer, for transdermal therapeutic systems according to [one or more of Claims 1 to 8] Claim 1, characterized in that to obtain absolutely impermeable metal layers, the vapour deposition is performed with the aid of a plasma in at least one operation.

11. (Amended) Use of plastic films according to [Claims 1 to 10] Claim 1 for manufacturing dermal or transdermal therapeutic systems containing readily volatile active agents or auxiliary agents.

Plastic films, especially for use in a dermal or transdermal therapeutic system

This invention relates to plastic films, which are coated on both sides with vapour-deposited metal and are meant to be used, in particular, for reducing the uptake of active substances in a dermal or transdermal therapeutic system, comprising a sheet-like substrate or reservoir containing readily volatile auxiliary agents and/or active agents, which substrate or reservoir is covered on one of its surfaces with a backing layer impermeable to the ingredients and on the opposite side with a detachable protective layer to prevent loss of ingredients during prolonged storage.

Transdermal therapeutic systems (TTSs) commonly comprise a backing layer impermeable to active or auxiliary agents, an active agent-containing layer and a detachable protective layer. The material from which the impermeable backing layer and the removable protective layer are made is commonly selected so as to absorb as little active substance as possible.
In the case of readily evaporating active agents such as nitroglycerine and nicotine, however, the selection of the materials turns out to be difficult. According to the state of the art, plastic films are used which are unilaterally metallized on the side which comes into contact with the active agent-containing layer. This measure, however, fails to satisfactorily prevent active substance loss, which loss occurs as a result of active substance escaping from the cutting edges of the transdermal therapeutic system, precipitating on the exposed side of the impermeable backing layer and the detachable protective layer, and being absorbed by the material of these layers.

EP 0 186 019 describes, in Example 1, a transdermal therapeutic system, which contains in its active substance-containing layer nitroglycerine adsorbed to lactose. During storage, however, the active ingredient-containing layer experiences a loss in nitroglycerine, namely approximately 16% over a period of 12 months. This means that the known transdermal therapeutic system is unstable and does not comply with pharmaceutical requirements.

DE 33 15 272 describes a transdermal therapeutic sytem having a layered active substance reservoir structure. According to Example 1, nitroglycerine adsorbed to lactose is used as active agent. As cover layer and/or for the removable protective layer, films are used that are made of various polymeric substances, such as polyethylene terephthalate, which may be aluminized on one side. However, the results obtained from stability tests show that in the course of 15 months the reservoir layer loses about 11% of nitroglycerine, about 6% of which are present in the cover layer and about 5% in the removable protective layer. From the pharmaceutical point of view, a loss of active substance of approximately 11% in 15 months is unacceptable.

The object of the present invention is to provide a dermal or transdermal therapeutic system containing readily volatile active agents or auxiliary agents which is formed such that, obviating the difficulties and technical restrictions existing in the state of the art and leading to loss of active and auxiliary agents, such loss is almost entirely prevented, even in the case of prolonged storage.

It has turned out, surprisingly, that this object is achieved by double-face vapour deposition of metal on plastic films according to the main claim.

The amount of metal vapour-deposited on the plastic films may be 10-500 mg/m², but preferably 40-200 mg/m², per side, the plastic films preferably being aluminized.

The plastic films provided on both sides with vapour-deposited metal may be rendered abhesive on one or on both sides. This is necessary above all if the plastic film provided with double-side metallization is used as a detachable protective layer. To render the double-side-metallized plastic films abhesive, one commonly employs silicone polymers.

The plastic films may be selected from the group of polyester, polyethylene, polypropylene, polyamide, polyurethane, polyvinyl chloride, polyvinylidene chloride, polyvinyl alcohol and ethylene-vinyl acetate copolymer.

For vapour deposition of metals, the plastic films may be employed on their own, but they can also be combined with each other. Thus, the plastic film may also be a laminate of two or more, different, layers of plastic.

Commonly, the plastic films have a thickness from 0.004-1.0 mm, preferably 0.010-0.5 mm.

The plastic films provided on both sides with vapour-deposited metal, which may in addition be rendered abhesive, are preferably used in the manufacture of sheet-like medicaments comprising readily volatile ingredients.

The double-face vapour deposition of metals on the plastic films takes place under high-vacuum or with the aid of a plasma, and can be carried out in one or more operations.

Example 1

In a thin-layer-chromatography glass chamber was placed enough nitroglycerine lactose trituration (10% nitroglycerine) for the bottom to be well covered. In the vapour chamber were hung film samples (16 cm^2), and placed in a drying cabinet heated to 40 °C. At time intervals of 1.2 or 3 months, respectively, samples were taken. These samples were rinsed with methanol to remove the adsorbed active agent. Then the test samples were exhaustively extracted with methanol, and the active substance was determined.

Table 1

Type of Film: *100 µm PET*	*Nitroglycerine Content ($\mu g/cm^2$)* *Storage Time (months)*		
	1	2	3
siliconized on both sides	0,96	0,88	1,28
aluminized on one side and siliconized on both sides	0,71	0,55	0,85
aluminized on both sides and siliconized on both sides	0,05	0,12	0,11

As shown by the results (Tab. 1), a PET film (100 µm) which is aluminized on both sides and siliconized on both sides absorbs only about 1/10 of the amount of nitroglycerine absorbed by a non-aluminized film (with 3 months' storage at 40 °C).

Example 2

The test conditions were analogous to those in Example 1; as active substance nicotine was used.

Table 2

Type of Film: *100 µm PET*	*Nicotine (µg/cm²)* *Storage Time (months)*		
	1	2	3
siliconized on both sides	0,24	0,59	0,75
aluminized on one side and siliconized on both sides	0,22	0,41	0,68
aluminized on both sides and siliconized on both sides	0,05	0	0,17

As verified by the results, here too, double-face aluminizing has clearly reduced the active substance absorption of a 100 µm PET film.

C L A I M S

1. Dermal or transdermal therapeutic system comprising a sheet-like substrate or reservoir containing readily volatile auxiliary agents or active agents, which substrate or reservoir is covered on one of its sides with a backing layer impermeable to the ingredients and on the opposite side with a detachable, likewise impermeable protective layer to prevent loss of ingredients during prolonged storage, characterized in that
both the backing layer and the protective layer are made of plastic film which is impermeably coated on both sides with vapour-deposited metal.

2. Therapeutic system according to Claim 1, characterized in that the amount of metal which is vapour-deposited per unit area is preferably 10 to 500 mg/m², and more preferably 40 to 200 mg/m².

3. Therapeutic system according to one or more of Claims 1 to 2, characterized in that the vapour-deposited metal is aluminium.

4. Therapeutic system according to one or more of Claims 1 to 3, characterized in that the plastic films of the protective layer, which are provided with a vapour-deposited metal layer, are rendered abhesive on at least one side.

5. Therapeutic system according to one or more of Claims 1 to 4, characterized in that the plastic films are selected from the group of polyester, polyethylene, polypropylene, polyamide, polyurethane, polyvinyl chloride, polyvinylidene chloride, polyvinyl alcohol and ethylene-vinyl acetate copolymer.

6. Therapeutic system according to one or more of Claims 1 to 5, characterized in that the plastic films have a thickness between 0.004 to 1.0 mm, preferably between 0.010 and 0.5 mm.

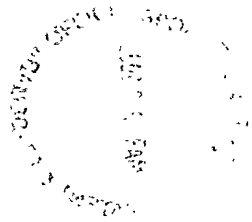
7. Therapeutic system according to one or more of claims 1 to 6, characterized in that it contains nitroglycerine as ingredient.

8. Therapeutic system according to one or more of Claims 1 to 6, characterized in that it contains nicotine as ingredient.

9. Process for the manufacture of plastic films provided with a vapour-deposited metal layer, characterized in that to obtain absolutely impermeable double-face metal layers, the vapour deposition is performed under high vacuum in at least one operation.

10. Process for the manufacture of plastic films provided with a vapour-deposited metal layer, characterized in that to obtain absolutely impermeable metal layers, the vapour deposition is performed with the aid of a plasma in at least one operation.

11. Use of plastic films according to Claims 1 to 10 for manufacturing dermal or transdermal therapeutic systems containing readily volatile active agents or auxiliary agents.



ABSTRACT

A dermal or transdermal therapeutic system comprising a sheet-like substrate or reservoir containing readily volatile auxiliary agents or active agents, which substrate or reservoir is covered on one of its sides with a backing layer impermeable to the ingredients and on the opposite side with a detachable, likewise impermeable protective layer to prevent loss of ingredients during prolonged storage, is characterized in that both the backing layer and the protective layer are made of plastic film which is impermeably coated on both sides with vapour-deposited metal.

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PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT AND DESIGN APPLICATIONS

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Insert Title: PLASTIC FILMS, ESPECIALLY FOR USE IN A DERMAL OR TRANSDERMAL THEREPEUTIC SYSTEM

Fill in Appropriate Information - For Use Without Specification Attached:

the specification of which is attached hereto. If not attached hereto,
the specification was filed on March 8, 2002 as
United States Application Number _____;
and amended on _____ (if applicable) and/or
the specification was filed on _____ as PCT
International Application Number _____; and was
amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representative or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Insert Priority Information: (if appropriate)

Prior Foreign Application(s)			Priority Claimed	
199 43 317.8 (Number)	Germany (Country)	September 10, 1999 (Month/Day/Year Filed)	☒ Yes	☐ No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	☐ Yes	☐ No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	☐ Yes	☐ No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	☐ Yes	☐ No

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional applications(s) listed below.

Insert Provisional Application(s): (if any)

_____ (Application Number) _____ (Filing Date)
_____ (Application Number) _____ (Filing Date)

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More than 12 Months (6 Months for Designs) Prior to the Filing Date of This Application:

Insert Requested Information: (if appropriate)

Country	Application Number	Date of Filing (Month/Day/Year)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States and/or PCT application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States and/or PCT application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Insert Prior U.S. Application(s): (if any)

(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)

Attorney Docket No.

I hereby appoint the practitioners at **CUSTOMER NO. 2292** as my attorneys or agents to prosecute this application and/or an international application based on this application and to transact all business in the United States Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the practitioners, unless the inventor(s) or assignee provides said practitioners with a written notice to the contrary:

Send Correspondence to:

BIRCH, STEWART, KOLASCH & BIRCH, LLP or **CUSTOMER NO. 2292**
P.O. Box 747 • Falls Church, Virginia 22040-0747
Telephone: (703) 205-8000 • Facsimile: (703) 205-8050

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor: Insert Name of Inventor → Insert Date This Document is Signed → Insert Residence Insert Citizenship → Insert Post Office Address →

1-00

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
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Full Name of Second Inventor, if any: see above

2-00

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
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MAILING ADDRESS (Complete Street Address including City, State & Country)		
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Full Name of Third Inventor, if any: see above

3-00

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Ursula GOTTE	Ursula Götte	08.04.2002
Residence (City, State & Country)		CITIZENSHIP
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MAILING ADDRESS (Complete Street Address including City, State & Country)		
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Full Name of Fourth Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

Full Name of Fifth Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

Full Name of Sixth Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

*DATE OF SIGNATURE